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(54) DEVICE AND METHOD FOR MEASURING COAGULATION TIME AND PLATELET ACTIVITY

(57) The present invention refers to a novel device for measuring coagulation time and platelet activity wherein the patient can measure his or her coagulation time and platelet activity without the aid of medical professionals due to the fact that this device is fully autonomous. A blood sample (14) is deposited in the dish (3) and reacted with a reactant (16). The display (9) then shows the coagulation time and platelet activity of the patient.

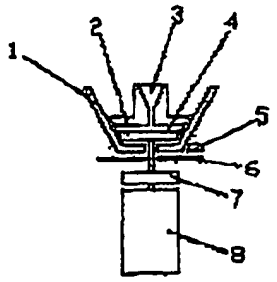

FIGURE 1

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Description

Object of the Invention

[0001] The present invention refers to a novel device for measuring coagulation time and platelet activity and to a process thereof, whereby, thanks to this electromechanically-operated, small-sized and battery-powered device, a patient can measure his or her coagulation time and platelet activity without the aid of medical professionals, furthermore being able to be connected to the medical center responsible for the patient clinical follow-up by means of telephone, Internet network or any other communication means.

Background of the Invention

[0002] The traditional method regarding measuring coagulation time and platelet activity of a patient hitherto has consisted of the analysis of these parameters in a clinical laboratory, by means of using instruments situated in clinical analysis laboratories, which implies frequent trips for patients, with the resulting social and financial damage for them, as well as for public health institutions, in addition to usually not being carried out with the periodicity recommended by medical specialists.

[0003] All the drawbacks mentioned above are emphasized when the measurement of coagulation time and platelet activity is carried out on a patient with cardiovascular diseases, given that these patients are treated with anticoagulant products with personalized doses for each patient.

[0004] These doses depend to a large extent on the blood characteristics of each patient, the two most important ones being those characterized by the parameters called "coagulation time" and "platelet activity", therefore they must periodically come to a clinical analysis laboratory to carry out the corresponding analyses in order to measure said parameters.

Description of the Invention

[0005] With the device for measuring coagulation time and platelet activity and process thereof, object of the present invention, all the drawbacks mentioned above are intended to be palliated or improved, to which end it is a measuring process by means of using a device in which a blood drop of the patient is introduced, such that this blood falls in the device, reacting with a reactant which is incorporated in the device whereby a change of the blood state is achieved and, thanks to this change, the coagulation time and platelet activity can be measured. To that end, it is a device made up of:

[0006] A frustoconical-shaped cup inside of which a likewise frustoconical-shaped rotor rotates, with the same taper but of a slightly smaller diameter.

[0007] The blood with the reactant is placed in the gaps between the rotor and the cup, the reactant serving as the coagulation precursor whereby a clot is formed in the gap, causing a decrease of the rotating speed of the rotor. This speed decrease is measured by a speed sensor and interpreted by an electronic circuit, resulting in the measurement of the coagulation time and/or platelet activity.

[0008] The operating of this device is by means of using batteries, which grants this device an obvious autonomy.

Description of the Drawings

[0009] To complement the description being made and for the purpose of helping to better understand the features of the invention, a series of drawings is attached to the present specification as an integral part thereof, in which with an illustrative and non-limiting character, the following has been shown:

Figure 1 shows a schematic view of the process for obtaining the measurement of the "coagulation time" and "platelet activity" parameters.

Figure 2 shows a view of mechanical operating of the invention,

Figure 3 shows a view of the interconnection of the components.

Preferred Embodiment of the Invention

[0010] As can be seen in the figures, a blood sample (14) placed in the dish (3) which is connected with the diametrical conduit (4) which has the reactant (16), is distinguished in the first place. This blood sample (14) together with the reactant (16) is ejected to the gap generated between the cup (1) and the rotor (2), thanks to the aid of the centrifugal force generated by the circular motion of the rotor (2) rotating due to the action of the electric motor (8), a speed sensor (7) is also observed, intended for measuring the speed decrease of the rotor (2) caused by a clot (15) formation, a result of the union of the blood sample (14) and the reactant (16); finally, a heating element (6) intended for maintaining the assembly at a temperature between 35 and 40 degrees centigrade and its corresponding temperature sensor (5) intended for assuring this temperature range are observed.

[0011] More specifically, the measuring device (13) is constituted of a small frustoconical or cylindrical-shaped cup (1), inside of which concentrically rotates a likewise frustoconical-shaped rotor (2) element with the same taper and slightly smaller diameter, such that there is a small clearance between both and there is no friction between the side walls of both elements nor between the bases.

The blood sample (14) of the patient and a reactant (16) functioning as a coagulation activator, are placed in the gaps between the interior rotor (2) and the

cup (1). The reactant (16) to be used will depend on whether the so-called "coagulation time" or "platelet activity" is to be measured.

[0012] Due to the rotation of the rotor (2), both products are thoroughly mixed, a biochemical process which, after a certain time, gives rise to the clot (15) formation being initiated, causing an increase of mechanical friction between the rotor (2) and the cup (1) detected due to its effect on the speed and on the torque of the cylinder.

[0013] In the event that the coagulation time is being measured, friction will suddenly increase in the moment in which clot (15) is produced. The time elapsed between the start of the process and the moment in which the friction increase occurs is measured by a control circuit (11), and with the due corrections automatically carried out, the so called "coagulation time" is obtained.

[0014] If "platelet activity" is being measured, the friction increase will be progressive in accordance with clot (15) formation and the manner in which it varies will be analyzed by the control circuit (11) to measure said parameter.

[0015] Given that the entire process must be carried out in a temperature range of 35 to 40°C, a heating element (6) and a temperature sensor (5) are incorporated under the cup (1). The control circuit (11) is in charge of maintaining the cup (1) and the rotor (2) at said temperature and of notifying the patient by the display (9) that the measuring device (13) is ready to be used once said temperature is reached and stabilized.

[0016] For the purpose of facilitating the dosage of the reactant (16) and of the patient blood sample (14), the rotor (2) has a diametrical conduit (4) in which the reactant (16) is housed.

[0017] For the purpose of facilitating the placing and subsequent dosage of the patient blood sample (14), the rotor (2) has a small dish (3) in the center of the upper face, which is connected at its lower portion with the center of the diametrical conduit (4) containing the reactant (16).

[0018] Once the measuring device (13) is on, and the time necessary to reach the operating temperature has elapsed, which is indicated to the patient by means of a small display (9), the patient will place a blood sample (14), obtained by a finger puncture, in the dish (3) intended for that purpose. The patient will then indicate to the measuring device (13) by means of the keyboard (10) that the measuring process can begin.

[0019] Said process begins with the phase of ejecting the reactant (16) and the blood sample (14) required for the clot (15) formation to occur. For that purpose, the rotor (2) is subjected to a very high rotating speed by means of an electric motor (8), the rotating shaft of which is solidly attached thereto, whereby, due to the centrifugal force, the reactant (16) will be ejected to the gap existing between the rotor and the cup.

[0020] Due to the vacuum generated in the diametrical conduit (4) of the rotor (2) due to the ejection of the reactant (16) contained therein, the blood sample (14), previously placed in the dish (3) located in the upper portion of the rotor (2), is also ejected towards said gap where, aided by the rotating motion, it is mixed with the reactant (16), the coagulation process itself beginning in that moment.

[0021] The amount of the ejected blood sample (14) will depend on the rotating speed of the rotor (2) and on the time the latter is rotating at high speed. Both parameters are controlled by the control circuit (11).

[0022] Once the reactant (16) and the blood sample (14) are ejected, the rotor (2) begins to rotate at a very slow speed. in this phase of the process, the control circuit (11) is in charge of measuring and controlling, the speed and torque of the motor solidly attached to the rotor (2) by means of the speed sensor (7). The increases in the braking torque or decreases of the speed will indicate that coagulation is taking place. A calculation, carried out by the control circuit (11) from said variations according to the time, will serve for measuring the parameter object of the analysis.

[0023] The control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for providing the necessary energy to the heating element (6) once the user activates the cycle start order by means of the keyboard (10), until the temperature sensor (5) indicates to the user that the suitable temperature has been reached,' at which time the patient will be notified by means of the display (9) that he or she can place the blood sample (14) in the dish (3).

[0024] The control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for providing the necessary power to the electric motor (8) by means of the power supply unit (12) once the patient has placed the blood sample (14) in the dish (3), such that the rotor (2) rotates at the required speed and for the necessary time to eject the reactant (16) contained in the diametrical conduit (4) of the rotor (2) due to the effect of centrifugal force, as well as the blood sample (14) placed in the dish (3), due to the effect of the vacuum generated due to the ejection of the reactant, and likewise to the centrifugal force.

[0025] The control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for providing the necessary power to the electric motor (8) by means of the power supply unit (12) so that the motor rotates at a certain speed once the ejection cycle of the reactant (16) contained in the diametrical conduit (4), and of the blood sample (14) previously placed in the dish (3), has concluded.

[0026] The control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for knowing at all times the rotating speed during the rotating phase of the rotor (2), thanks to the speed sensor element (7) con-

nected thereto, as well as the braking torque exerted by the clot (15) formation located in the gap existing between the rotor (2) and the cup (1) by measuring the current consumption of the motor (8).

[0027] The control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for being able to carry out the necessary calculations from the obtained rotating speed and braking torque values according to what is indicated in the previous paragraph, designed for obtaining the parameters called "coagulation time" or "platelet activity" as appropriate.

[0028] Having sufficiently described the nature of the present invention, as well as a manner of taking it to practice, all that remains is to add that it is possible to introduce changes in shape, materials and arrangement in the invention as a whole and in parts making it up, as long as said changes do not substantially change the features of the invention which are claimed below:

Claims

1. A coagulation time and platelet activity measuring device and a process thereof, of those constituted of an electromechanical device controlled by a control circuit (11), intended to be used by patients without the direct intervention of medical professionals, **characterized in that** once the patient orders the start of the cycle by means of using the keyboard (10) in the measuring device (13), and a blood sample (14) is placed in the dish (3), which is connected with the diametrical conduit (4) which has the reactant (16) where this blood sample (14) together with the reactant (16) is ejected to the gap created between the cup (1) and the rotor (2), thanks to the aid of the centrifugal force generated by the circular motion of the rotor (2), rotating due to the action of the electric motor (8), fed by a power supply unit (12), such that a speed sensor (7) measures the speed decrease of the rotor (2) caused by a clot (15) formation, a result from the union of the blood sample (14) and the reactant (16); a heating element (6) and its corresponding temperature sensor (5) are furthermore provided, all this controlled by a control circuit (11), interconnected with all the elements, such that the coagulation time and platelet activity parameters are shown on the display (9).

2. A coagulation time and platelet activity measuring device and process thereof according to claim 1, **characterized in that** the cup (1) is constituted of an intemally frustoconical-shaped recipient open at the upper face, provided with an opening at the lower face intended for allowing the passage of a rotating shaft.

3. A coagulation time and platelet activity measuring device and process thereof according to claim 1, **characterized in that** inside the frustoconical-shaped cup (1), a likewise frustoconical-shaped rotor (2) element with the same taper and slightly smaller diameter concentrically rotates, such that there is a small clearance between both and there is no friction between the side walls of both elements nor between the bases.

4. A coagulation time and platelet activity measuring device and process thereof according to the previous claim, **characterized in that** the rotor (2) incorporates a diametrical conduit (4) intended for containing the reactant (16) triggering the coagulation process.

5. A coagulation time and platelet activity measuring device and process thereof according to claim 3, **characterized in that** the rotor (2) incorporates a dish (3) on its upper face, connected with the center of the diametrical conduit (4), intended for receiving the patient blood sample (14).

6. A coagulation time and platelet activity measuring device and process thereof according to claim 1, **characterized in that** the temperature provided by the heating element (6) to the rotor (2) and cup (1), is determined by the temperature sensor (5) and controlled by the control circuit (11).

7. A coagulation time and platelet activity measuring device and process thereof according to the previous claim, **characterized in that** the temperature of the gap of the rotor (2) and the cup (1) is in the range of 35 to 40°C.

8. A coagulation time and platelet activity measuring device and process thereof according to claim 1, **characterized in that** the electrically operated motor (8) causes the rotation of the rotor (2).

9. A coagulation time and platelet activity measuring device and process thereof according to the previous claim, **characterized in that** the rotor (2) rotates at a high speed so that the ejection of the reactant (16) and of the blood sample (14) is caused due to the effect of the centrifugal force, all this by means of control of the control circuit (11).

10. A coagulation time and platelet activity measuring device and process thereof according to claim 8, **characterized in that** the control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for knowing at all times the rotating speed during the rotation phase of the rotor (2), thanks to the speed sensor (7) element connected thereto, as well as by measuring the current consumption of the

motor (8), the braking torque exerted by the clot formation (15) located in the gap existing between the rotor (2) and the cup (1).

11. A coagulation time and platelet activity measuring device and process thereof according to the previous claim, **characterized in that** the control circuit (11) is configured as a device provided with the electronic and electric components and automatisms necessary for being able to carry out necessary calculations from the obtained rotating speed and braking torque values, designed for obtaining the parameters called "coagulation time" or "platelet activity" as appropriate and show them on the display (9).

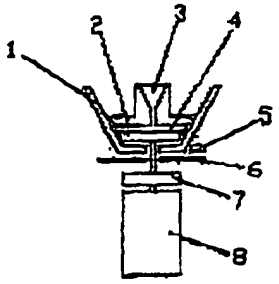

FIGURE 1

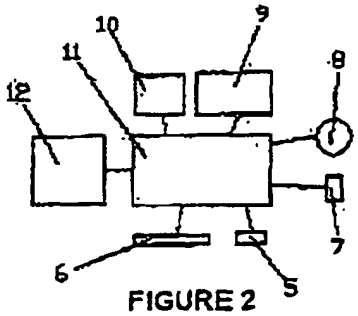

FIGURE 2

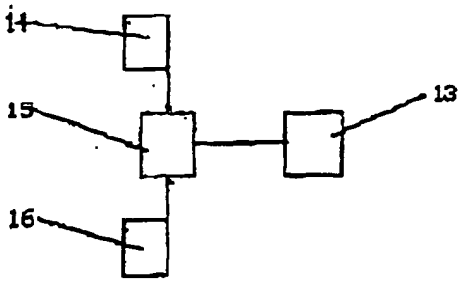

FIGURE 3